K050470
1 of 2

MAY - 6 2005

510(k) Summary

General Information

Classification	Class II, Arterial Embolization Device per 21 CFR § 870.3300
Trade Name	Concentric Embolic Pearls™
Submitter	Concentric Medical, Inc. 1380 Shorebird Way Mountain View, CA 94043 tel: 650-938-2100
Contact	Jean M. Caillouette, RAC Manager, Regulatory Affairs

Intended Use

The Concentric Embolic Pearls are intended for use in the embolization of hypervascularized tumors in the peripheral vasculature.

Predicate Devices

EMBOSPHERE® Microspheres K991549
Manufactured by Biosphere Medical, Inc.

EmboGold™ Microspheres K010026
Manufactured by Biosphere Medical, Inc.

TruFill™ PVA Particles K951314, K965174
Manufactured by Cordis Endovascular Systems

Device Description

The Concentric Embolic Pearls are non-resorbable, hydrogel-based spherical microbeads. The Embolic Pearls are delivered via a catheter in an amount and size appropriate for the targeted area. The Embolic Pearls slow/stop blood flow to hypervascularized tumors by occluding the blood vessel which provides blood flow to the tumor.

Materials

All materials used in the manufacture of the Concentric Embolic Pearls are suitable for the intended use of the device.

Testing Summary

The Concentric Embolic Pearls have successfully passed all performance and functional testing performed demonstrating that the device performs in accordance with the requirements of the Product Specification. In all biocompatibility studies performed, the results for the Concentric Embolic Pearls was substantially equivalent to the negative control article and no significant adverse reactions were noted in any study conducted. Results of chemical assays performed clearly demonstrate that no harmful levels of

residuals, monomers, or leachables are detectable in the Concentric Embolic Pearls following hydration. Results of *in-vivo* animal testing performed demonstrated consistent delivery of the Embolic Pearls to the treatment site, that no vessel damage occurs when the Embolic Pearls are deployed to the treatment site, and overall, the Embolic Pearls performed similarly to the EmboGold Microspheres.

Summary of Substantial Equivalence

All characteristics/attributes of the Concentric Embolic Pearls are either identical or substantially equivalent to the existing legally marketed predicate devices identified in this application. As such, Concentric Medical, Inc. believes the Concentric Embolic Pearls are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2005

Concentric Medical, Inc.
c/o Ms. Jean M. Caillouette, RAC
1380 Shorebird Way
Mountain View, CA 94043

Re: K050470
Trade Name: Embolic Pearls
Regulation Number: 21 CFR 870.3300
Regulation Name: Arterial embolization device
Regulatory Class: II (two)
Product Code: KRD
Dated: February 18, 2005
Received: February 23, 2005

Dear Ms. Caillouette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050470

Concentric Medical, Inc.
Concentric Embolic Pearls™

Indications for Use

510(k) Number (if known):	This application K050470
Device Name:	Concentric Embolic Pearls™
Indications for Use:	The Concentric Embolic Pearls™ are indicated for use in the embolization of hypervascularized tumors in the peripheral vasculature.

Prescription Use _X_ OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vachuss

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K050470